DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2388n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 22 1999

WARNING LETTER
FEDERAL EXPRESS

Mr. Laurent Francfort
CFG S.A. Microelectronic
Avenue de Lonay 2 –2bis
CH-1110 Morges, Switzerland

Dear Mr. Francfort:

We are writing to you because on November 11, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving a product known as the Compex 2.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body.

In legal terms, the product is adulterated under section 501(h) of the Act because the methods, controls or facilities used in the manufacture of the product do not comply with the FDA Quality System Regulation (QS Reg). At the conclusion of the inspection, the investigator discussed with you items regarding Quality System Regulation deficiencies:

1. Failure to establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services.

   For example, "standard" components are not tested upon incoming receipt and only the packing list is verified. On September 10, 1998, your firm received 5,250 Q21 (16-amp) power module transistors. None of the Q21 power module transistors were sampled, inspected, or tested prior to acceptance or upon incoming receipt. Additionally, on September 25, 1998, your firm received 5,167 microcontrollers (central unit computers). None of the microcontrollers were sampled, inspected, or tested prior to acceptance or upon incoming receipt.

2. Failure to conduct a quality audit to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

   For example, the component suppliers have not been audited or qualified.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter the steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. If the documentation is not in English, please provide a translation to facilitate our review. Please address your response to:

Edgardo Santiago
Food and Drug Administration
Center for Devices and Radiological Health
Division of Enforcement III
Orthopedic, Physical Medicine & Anesthesiology Devices Branch
2098 Gaither Road
Rockville, MD 20850

If you have any questions, please contact Carol Arras at (301) 594-4659.

Sincerely yours,

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

Frederic-Edouard Koehn
Chief Executive/CEO
Compex S.A.
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